

PRN 96-4: Label Statements Involving Product Efficacy and Potential for Harm to Property

June 3, 1996

Notice To: Manufacturers, Producers, Formulators, and Registrants of Pesticide Products

Attention: Persons Responsible for Federal Registration and Reregistration of Pesticide Products

Subject: Label Statements Involving Product Efficacy and Potential for Harm to Property

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I. Introduction

This notice explains EPA procedures in approving pesticide labels that include claims relating to the efficacy of agricultural pesticides and provides a warning to growers regarding reliance on label statements regarding pesticide efficacy. EPA is issuing this notice at this time to correct a misunderstanding regarding the FIFRA label approval process and efficacy claims that is reflected in a series of court decisions concerning the preemptive effect of FIFRA.

II. Legal Framework

a. Registration And The Label Approval Process

EPA approves pesticide labels in the process of registering a pesticide under FIFRA. FIFRA specifies that EPA shall register a pesticide if:

- i. its composition is such as to warrant the proposed claims for it;
- ii. its labeling and other material required to be submitted comply with the requirements of this Act;
- iii. it will perform its intended function without unreasonable adverse effects on the environment; and
- iv. when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.
- v.
- vi.

7 U.S.C. 136c(c)(5). Although the first registration requirement identified above mandates that EPA consider efficacy of label claims, Congress, in 1978, explicitly gave EPA the authority to waive that requirement. FIFRA states:

In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the

pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy.

7 U.S.C. 136c(c)(5). The legislative history explains that Congress believed that product performance issues for agricultural pesticides were adequately addressed by information from government and university sources and market forces:

This authority [to waive efficacy data] will be used most commonly with respect to agricultural pesticides, due to the high level of knowledge concerning pesticidal efficacy that prevails in the agricultural community, the existence of means for communicating efficacy information to users, the organizational expertise of the Department of Agriculture, the extension services, and the universities in this area, and the stake the industry has in marketing products that are efficacious.

S. Rpt. 95-334, 95th Cong., 1st Sess. 20 (July 6, 1977).

EPA has acted under this authority to waive, by regulation, data requirements as to efficacy issues for all agricultural pesticides. 44 Fed. Reg. 27932, 27938 (col. 3) (May 11, 1979); 40 CFR 158.640(b)(1); see also 47 Fed. Reg. 57624 (December 27, 1982). EPA concluded that agriculture pesticides are "effectively regulated by the marketplace," 44 Fed. Reg. 27932, 27938 (col. 3) (May 11, 1979), and that waiving review of the efficacy of agricultural pesticides in the registration process would enable the Agency to focus of its "primary mandate under FIFRA": investigating "the health and safety aspects of pesticides." 47 Fed. Reg. 53192 (November 24, 1982); 47 Fed. Reg. 40659, 40661 (col.1) (September 15, 1982). EPA pointed to private legal actions for damages as one factor that would ensure that pesticide manufacturers sold an efficacious product: "pesticide producers are aware that they are potentially subject to damage

suits by the user community if their products prove ineffective in actual use." 47 Fed. Reg. 40659, 40661 (col.2) (September 15, 1982).

EPA has also, by regulation, promulgated various requirements pertaining to pesticide labels. These regulations bar the registration of any pesticide with a misbranded label, 40 C.F.R. 152.112(f), and contain specific examples of label statements that are considered false or misleading and thus render a label misbranded. 40 C.F.R. 156.10(a)(5). Additionally, the regulations have requirements for warning statements and mandate that pesticide products have adequate use directions. 40 C.F.R. 156.10(h) and (i).

b. State Preemption Under FIFRA

FIFRA permits states broad authority to regulate pesticides but makes it unlawful for states that undertake such regulation to "impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act." 7 U.S.C. 136v(b). A number of federal court decisions have held that this preemption of state authority as to pesticide labels bars damage claims in state court by growers against pesticide manufacturers. The courts have reasoned that allowing such a claim by a grower would be, in effect, permitting the state to impose label requirements "in addition to or different from" the federally-approved label.

III. Label Approval And Pesticide Efficacy

There have been several recent preemption decisions involving claims by growers concerning pesticidal efficacy or property damage caused by a pesticide. For example, in *Taylor Ag Industries v. Pure-Gro*, 54 F.3d 555 (9th Cir. 1995), several growers sued the manufacturers and distributor of a pesticide that the growers alleged had damaged their cotton crop even though they had applied the pesticide according to the label directions. The court denied the growers' claims on the ground that allowing recovery of damages would interfere indirectly with EPA's "rigorous label-approval process." *Id.* at 560. In *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69 (8th Cir. 1995), and *Worm v. American Cyanamid, Inc.* 5 F.3d 744 (4th Cir. 1993), growers sued a pesticide manufacturer seeking recovery for harm to crops allegedly caused when the manufacturer's herbicide remained in the soil and damaged rotated crops. Both courts dismissed the growers' claims noting that EPA's labeling regulations required instructions on rotational crop restrictions. The courts reasoned that to permit such lawsuits "would be to allow state courts to sit, in effect, as super-EPA review boards that could question the adequacy of the EPA's determination of whether a pesticide registrant successfully complied with the specific labeling requirements of its own regulations." *Welchert*, 59 F.3d at 73; *Worm*, 5 F.3d at 749.

These court decisions are based on the premise that, in approving labels for agricultural pesticides, EPA examines, or at least has the obligation to examine, the efficacy of the pesticide and related issues such as the potential for the pesticide to cause property damage. The courts, however, have not taken into account the plain language of the statute on this issue and have misinterpreted the thrust of EPA's regulations. As noted above, in actual fact, EPA, with Congress' approval, stopped evaluating pesticide efficacy for routine

label approvals almost two decades ago. Further, as explained below, EPA's regulations do not require a review of efficacy of property damage issues for agricultural pesticides.

EPA's labeling regulations must be interpreted in light of the statutory requirements for registration and EPA's waiver of the requirement for efficacy data on agricultural pesticides. Because efficacy data is not reviewed as part of the registration of agricultural pesticides, it would be incorrect to contend that the label approval process involves an examination of the efficacy of the pesticide. Rather, the label approval process is centered on the issue of whether label, including the specification of use sites and the directions for use on the label, meets the core requirement for registration: that the pesticide not cause "unreasonable adverse effects on the environment." That term is defined as "any unreasonable risk to man or the environment" 7 U.S.C. 136(bb). Accordingly, the primary focus in the label approval process for agricultural pesticides involves assessing and regulating the potential risks to humans and the environment posed by such pesticides.

To this end, EPA applies the requirements in its labeling regulations with an eye to risk not efficacy issues. This is illustrated by how EPA applies label requirements regarding pesticide use sites and directions for the use of pesticides including directions concerning rotational crops. Label regulations require that pesticide use sites (e.g., specific crops, animals, etc.) be listed on the label because assessment of the dietary risk of pesticides is based on the foods that legally may contain the pesticide, and, under FIFRA, the label establishes the legal limits on use of a pesticide. 7 U.S.C. 136j(a)(2)(G). Use sites are not reviewed as to the pesticide's efficacy for those crops. The label regulations address the directions for use of a pesticide for the purpose of insuring that pesticide applicators and farmworkers are adequately protected. Additionally, directions for

use establish legal limits as to the amounts of pesticide that may be applied and thus allow EPA to control and estimate dietary exposure. EPA does not check to see whether application equipment mentioned in directions for use will be harmed or whether other property damage might occur. For example, the label regulations on directions for use specify that rotation crop restrictions are required when needed "to prevent unreasonable adverse effects upon the environment." 40 C.F.R. 156.10(i)(2)(x). Such restrictions are needed for certain pesticides to prevent uptake of residual pesticide residues from the soil into crops for which the pesticide is not registered. EPA's concern is that the consumption of the rotated crop would increase dietary exposure to the pesticide residue. Rotational crop restrictions are not reviewed to determine if the rotated crop would be injured by the residual pesticide residues.

An additional requirement for registration, noted above, is that the pesticide's labeling comply with the Act. Separately, EPA, by regulation, has required that labeling not be misbranded. 40 C.F.R. 152.112(f). However, these registration requirements should not be read as reintroducing efficacy concerns into the label approval process. Having directly given EPA the authority to disregard efficacy issues, Congress could not have intended that, once EPA exercised this authority, the same efficacy issues would come in through the back door of the label approval process. Under the statute and its regulations, EPA still must determine in registering a pesticide if the pesticide's label complies with FIFRA or is misbranded but, unless EPA reinstates the requirement to submit efficacy data (either generally or with regard to a particular pesticide), that compliance and misbranding inquiry will generally not extend to the evaluation of the efficacy of the pesticide.

Efficacy and property damage issues are at times relevant to the continued registration of a pesticide. FIFRA's "unreasonable adverse effects" standard requires EPA to take into account "economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. 136(bb). A pesticide's efficacy and its potential to cause property damage are factors to be considered in determining the economic benefit a pesticide provides to farmers. However, in light of EPA's waiver of the efficacy data requirement for initial registration, these issues would generally only arise following the registration of the pesticide, including approval of the pesticide label. For example, if a pesticide manufacturer were to learn that one of its registered pesticides was causing property damage, the manufacturer would be obligated to report that information under section 6(a)(2) of the statute. 7 U.S.C. 136c(a)(2). Additionally, if EPA discovers new risk concerns with an already-registered pesticide, it might examine efficacy data with regard to the pesticide in making an evaluation under the unreasonable adverse effects standard to determine if the product's registration should be cancelled or suspended.

IV. Conclusion

EPA hopes this Notice will be useful to courts, the regulated community, and pesticide users. EPA believes this Notice should be helpful to courts in preemption cases that involve EPA's labeling regulations. For example, some courts have mistakenly assumed that EPA's labeling regulations concerning the directions for use of a pesticide have an efficacy component. Further, other courts have erroneously concluded that because a pesticide label contained warnings regarding property damage that EPA had necessarily evaluated such warnings and found them to be truthful and adequate. As to registrants and applicants for registration, this Notice is intended to confirm that EPA has not altered its regulation relating to the waiver of efficacy data requirements for the registration of agricultural pesticides. Finally, as to pesticide users this Notice is intended to clarify that EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage.

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